



JCOG Rec'd PCT/PTO 22 SEP 2005

Attorney Docket No. 1877.1001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Tai-Wha CHUNG et al.

Examiner: To Be Assigned

Application No.: 10/540,848

Group Art Unit: To Be Assigned

Filed: June 27, 2005

For: Monoclonal Antibody Against Asialo Alpha 1-Acid Glycoprotein, Immunochromatographic Strip Comprising The Monoclonal Antibody, And Method For Diagnosing Liver Diseases Using The Immunochromatographic Strip

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 CFR § 1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the subject application.

1. Enclosures accompanying this Information Disclosure Statement are:

- 1a. ☒ Form PTO-1449.
- 1b. ☒ Copy(ies) of IDS citation(s), except for U.S. Patents and U.S. Patent Application publications.
- 1c. ☒ English language copy of a communication(s) from a foreign Patent Office or a PCT International Search Report.
- 1d. ☐ English language translation (complete, Abstract or relevant portion(s)) attached to non-English language publications as indicated on the attached Form PTO-1449.
- 1e. ☐ Explanations of Relevancy of References (ATTACHMENT 1(e), hereto) for providing a concise explanation of non-English publications.
- 1f. ☐ List of Copending Applications (ATTACHMENT 1(f), hereto).
- 1g. ☒ List of Additional Submitted Documents (ATTACHMENT 1(g), hereto).

2. ☒ This Information Disclosure Statement is filed under 37 CFR § 1.97(b):

(Check either Item 2a or 2b or 2c or 2d)

- 2a. ☒ Within three months of the filing date of a national application;
- 2b. ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application.
- 2c. ☐ Before the mailing of a first Office Action on the merits; or
- 2d. ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114.

3. ☐ This Information Disclosure Statement is filed under 37 CFR § 1.97(c) after the period specified in paragraph 2 above but before the mailing date of any of a Final Office Action under § 1.113, a Notice of Allowance under § 1.311 or an action that otherwise closes prosecution in the application, AND

(Check either Item 3a or 3b; Item 3b to be checked if any reference known for more than 3 months)

- 3a. ☐ The § 1.97(e) Statement in Item 5 below is applicable; OR
 3b. ☐ The \$180.00 fee set forth in 37 CFR § 1.17(p) is:
☐ enclosed.
☐ to be charged to Deposit Account No. 19-3935.

4. ☐ This Information Disclosure Statement is filed under 37 CFR § 1.97(d) after the period specified in paragraph 3 above, but on or before payment of the Issue Fee, AND

- 4a. ☐ The § 1.97(e) Statement in Item 5 below is applicable; AND
 4b. ☐ The \$180.00 fee set forth in 37 CFR § 1.17(p) is:
☐ enclosed.
☐ to be charged to Deposit Account No. 19-3935.

5. ☐ Statement under § 1.97(e) (*applicable if Item 3a or Item 4a is checked*)
(Check either Item 5a or 5b)

- 5a. ☐ In accordance with 37 CFR § 1.97(e)(1), it is stated that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
 5b. ☐ In accordance with 37 CFR § 1.97(e)(2), it is stated that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known by any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

6. ☐ This is a continuation/divisional/continuation-in-part application under 37 CFR § 1.53(b).

(Check appropriate Items 6a and/or 6b)

- 6a. ☐ Copies of the publications listed on the attached Form PTO-1449 which were previously cited in prior application Serial No. ___, filed on ___, and which is relied on for an earlier effective filing date for the subject application under 35 U.S.C. § 120, have been omitted pursuant to 37 CFR § 1.98(d).
 6b. ☐ Copies of the publications listed on the attached Form PTO-1449 which were not previously cited in prior application Serial No. ___, filed on ___, and which is relied on for an earlier effective filing date for the subject application under 35 U.S.C. § 120, are provided herewith.

7. ☐ This is a Request for Continued Examination under 37 CFR § 1.114.
(Check either Item 7a or 7b)
- 7a. ☐ The Issue Fee has not been paid.
- 7b. ☐ A Petition to Withdraw from issue under 37 CFR § 1.313(c) is filed concurrently herewith or has been granted. A Request for Continued Examination under 37 CFR § 1.114, after payment of the Issue Fee, is proper in accordance with 37 CFR § 1.114(a), respectively.
8. ☐ This is a Supplemental Information Disclosure Statement.
(Check either Item 8a or 8b)
- 8a. ☐ This Supplemental Information Disclosure Statement under 37 CFR § 1.97(f) supplements the Information Disclosure Statement filed on _____. A bona fide attempt was made to comply with 37 CFR § 1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental IDS can be considered as if properly filed on _____.
- 8b. ☐ This Supplemental Information Disclosure Statement is timely filed within one (1) month of the Notice under 37 CFR §§ 1.97 and 1.98, mailed _____.
9. ☐ In accordance with 37 CFR § 1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
(Check appropriate Items 9a, 9b, 9c and/or 9d)
- 9a. ☐ satisfied for the non-English language publication(s) cited on the enclosed "English language version of the search report or action which indicates the degree of relevance found by the foreign office". (See MPEP § 609, Minimum Requirements for an Information Disclosure Statement, Part A(3): Concise Explanation of Relevance, 8th Ed., Rev. 2)
- 9b. ☐ set forth in the application.
- 9c. ☐ satisfied for the non-English language publication(s) indicated on the attached Form PTO-1449 as having an English language translation (complete or relevant portion(s)) attached thereto.
- 9d. ☐ enclosed as Attachment 1(e), hereto.
10. No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than search report(s) from a counterpart foreign application or a PCT International Search Report, if submitted herewith). 37 CFR §§ 1.97(g) and (h).

11. The Commissioner is authorized to credit any overpayment or charge any additional fee required under 37 CFR § 1.17 for this Information Disclosure Statement to Deposit Account No. 19-3935.

Respectfully submitted,

STAAS & HALSEY LLP

Dated: September 22, 2005
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Washington, D.C. 20005
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Facsimile: (202) 434-1501

By: Darleen J. Stockley
Darleen J. Stockley
Registration No. 34,257



Sheet 1 of 1

| | | |
|--|----------------------|-----------------|
| FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i> | ATTORNEY DOCKET NO. | APPLICATION NO. |
| | 1877.1001 | 10/540,848 |
| | FIRST NAMED INVENTOR | |
| | Tai-Wha CHUNG et al. | |
| | FILING DATE | GROUP/ART UNIT |
| | June 27, 2005 | |

U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | | DOCUMENT NO. | DATE | NAME | CLASS | SUB- CLASS | FILING DATE |
|----------------------|----|-----------------|------|------|-------|---------------|----------------|
| | AA | | | | | | |
| | AB | | | | | | |
| | AC | | | | | | |
| | AD | | | | | | |
| | AE | | | | | | |
| | AF | | | | | | |

FOREIGN PATENT DOCUMENTS

| | AG | DOCUMENT NO. | DATE | COUNTRY | TRANSLATION YES NO | | ABSTRACT |
|--|----|-----------------|----------|---------|-----------------------|--|----------|
| | AH | 01/35105 | 5/17/01 | WO | | | |
| | AI | 0 199 196 | 10/29/86 | EP | | | |
| | AJ | 98/22824 | 5/28/98 | WO | | | |
| | AK | | | | | | |

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | | TRANSLATION YES NO | |
|--|----|---|-----------------------|--|
| | AL | Kilian Dill et al., "Detection of human asialo- α_1 -acid glycoprotein using a heterosandwich immunoassay in conjunction with the light addressable potentiometric sensor", Glycoconjugate Journal, Vol. 13(4), pp. 637-641 (1996) | | |
| | AM | Fionnuala T. Lundy et al., "An Antibody – Lectin Sandwich Assay for Quantifying Protein Glycoforms", Molecular Biotechnology, Vol. 12(2), pp. 203-206 (1999) | | |

| | |
|----------|-----------------|
| EXAMINER | DATE CONSIDERED |
|----------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**ATTACHMENT 1(g)**

| | | |
|---|----------------------|-----------------|
| LIST OF ADDITIONAL SUBMITTED DOCUMENTS | ATTORNEY DOCKET NO. | APPLICATION NO. |
| | 1877.1001 | 10/540,848 |
| | FIRST NAMED INVENTOR | |
| | Tai-Wha CHUNG et al. | |
| | FILING DATE | GROUP ART UNIT |
| | June 27, 2005 | |

The following document(s) is/are listed in accordance with the duty of disclosure provisions of 37 CFR § 1.56, so that the Examiner may consider same should he deem any thereof to be material to examination of the subject application.

It is requested that the Examiner acknowledge his consideration of document(s) below-listed by initialing same in the space provided adjacent each such application and that the Examiner sign and date this form at the bottom thereof to confirm such consideration having been given.

This submission in no way represents an admission that any of the information listed herein constitutes prior art with respect to the subject application; and unless and until such prior art status is established, this submission is not a request that the information presented herein be printed on the face of any patent issuing from the subject application in which this information is being filed.

U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | | DOCUMENT NO. | DATE | NAME | CLASS | SUB- CLASS | FILING DATE |
|----------------------|----|-----------------|------|------|-------|---------------|----------------|
| | AA | | | | | | |
| | AB | | | | | | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NO. | DATE | COUNTRY | CLASS | SUB- CLASS | <u>TRANSLATION</u> YES NO | |
|--|----|-----------------|------|---------|-------|---------------|------------------------------|--|
| | AC | | | | | | | |
| | AD | | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | | <u>TRANSLATION</u> YES NO | |
|--|----|--|------------------------------|--|
| | AE | International Search Report for Application No. PCT/KR2003/002860, dated May 12, 2004. | | |

| | |
|---|-----------------|
| EXAMINER | DATE CONSIDERED |
| *EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |